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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,690	10/08/2003	Vincent Chau	MP197-057P1RCP1CNIM	7707

30405 7590 01/29/2007
MILLENNIUM PHARMACEUTICALS, INC.
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CAMBRIDGE, MA 02139.

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/681,690

Applicant(s)

CHAU, VINCENT

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30, 31, 34, 36, 38, 56 and 59-64 is/are pending in the application.
- 4a) Of the above claim(s) 34, 36, 38 and 59-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 and 56 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/07/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

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DETAILED ACTION

1. Claims 30, 31, 34, 36, 38, 56, 59-64 are pending in the instant application.
2. Applicants' request to examine amended claim 59 dated 11/07/2006 has been fully considered. However, the examiner maintains the position that the invention of Group X and invention of amended claim 59 are patentably distinct products because each of the products are independent chemical entities that require literature searches. Each of the products have different biological functions which require additional searches in the patent and non-patent literature, where the dominant negative conjugating enzyme recited in claim 59 has the opposite biological function compared to the recited wild-type conjugating enzyme of claim 30. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter.
Claims 34, 36, 38, and 59-64 have stand withdrawn from consideration as being directed toward a non-elected invention.
3. Claims 30, 31, and 56 are under consideration in this Office Action.
4. The objection to the title of the invention has been withdrawn in view of applicants' amendment to the title filed 11/07/2006.
5. The objection to the disclosure for failure to update the biographical information in the specification has been withdrawn in view of applicants' amendment to the specification filed 04/11/2006.
6. The objection to claims 30, 31, and 56 has been withdrawn in view of applicants' amendment to the claims, where the claims recite the definition of the abbreviations.
7. The rejection of claims 30, 31, and 56 under 35 U.S.C. 102(a) as being anticipated by Osaka et al. (Genes Dev. 1998 Aug 1;12(15):2263-8; and Accession P61081) has been withdrawn in view of applicants' Declaration under 37 C.F.R §1.131 filed 11/07/2006.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 30 and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified "Neural precursor cell-Expressed Developmentally Down regulated" (NEDD8)-conjugating enzyme comprising the amino acid sequence of SEQ ID NO: 4; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants' arguments filed 11/07/2006 have been fully considered but are not persuasive. The examiner respectfully disagrees with applicants' position that the specification provides guidance for making the invention for reasons of record as supplemented below.

Although the referenced international publication WO 95/189714 provides general information regarding how conservative substitutions can be made which may not affect biological activity, the reference and the specification does not provide guidance, prediction, and working examples for making any protein at least 95% identical to SEQ ID NO: 4 and any protein encoded by an expression element comprising a nucleic acid sequence at least 95% identical to SEQ ID NO: 3.

An undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any protein having at least 95% identity to SEQ ID NO: 4 or any protein encoded by any expression element comprising a nucleic acid sequence at least 95% identical to SEQ ID NO: 3, where said protein forms a thioester linkage with NEDD8. Alternatively, trial and error experimentation must then be performed to search and screen for specific amino acid residues in SEQ ID NO: 4 to change (e.g., amino acid deletion, insertion, substitution, and combinations thereof) or specific nucleotide to change in SEQ ID NO: 3 (e.g., nucleotide deletion, insertion, substitution, and combinations thereof) which will not result in inactivation of its biological function of forming a thioester linkage with NEDD8. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

Without specific guidance regarding the specific amino acid residues in SEQ ID NO: 4 and specific nucleotides in SEQ ID NO: 3 to change which does not affect enzyme activity, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation. Claim 56 is also included in the rejection because it does not

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correct the defect of claim 30.

Conclusion

10. No claims are allowed.

11. Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

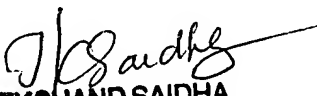
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

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TEKCHAND SAIDHA
PRIMARY EXAMINER